K112669

510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
TattooStar Effect Y

MAY 11 2012

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH TattooStar Effect Y is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Bruesseler Str. 10 07747 Jena, Germany
Contact Person:	Mrs. Antje Katzer Product Management and International Regulatory Affairs
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Preparation Date:	May 2nd , 2012
Device Name:	TattooStar Effect Y
Common Name:	TattooStar Effect Y
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 79-GEX 21 CFR 878.4810
Equivalent Devices:	TattooStar Y K071451 Spectra K103455 Dermablate Effect K081541 Aluma K051214 Ellipse Flex PPT K052688
Device Description:	The TattooStar Effect Y is a pulsed Nd:YAG solid state laser emitting wavelengths of 1064nm and 532nm. The beam can be converted to 585nm by means of an optional dye handpiece. The laser system can optionally be equipped with a pulsed light module (APL), a radiofrequency module (RF) and an acoustic wave module (AW).

Intended Use: The TattooStar Effect Y laser is indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair and skin resurfacing procedures.
For the specific wavelengths of the TattooStar Effect Y the indications are as follows:

532 nm:	Removal of pigmented lesions (including but not limited to lentigo benigna, hyperpigmented burn and boil scar, naevus Ota / Ito, freckles, Becker naevi, Café-au-lait spots)
	removal of red tattoo inks
	removal of minor vascular lesions
1064 nm:	removal of black and dark blue tattoo inks
	removal of unwanted hair
	skin resurfacing
585 nm:	removal of sky blue tattoo inks

The Asclepion Pulsed Light of the TattooStar Effect Y is intended for permanent hair reduction, treatment of vascular lesions, pigmented lesions and inflammatory acne.

Depending on the different filters, the indications are as follows:

400 – 750 nm:	Acne
500 – 1200 nm:	Hair removal of blond hair, skin type I-II
	Vascular lesions, skin type I-II
550 – 1200 nm:	Hair removal of brown and black hair, skin type I-II
	Hair removal of blond, brown and black hair, skin type III
	Vascular lesions, skin type III-IV
	Pigmented lesions, skin type I-IV
650 – 1200 nm:	Hair removal of black hair, skin type IV

The Radiofrequency of the TattooStar Effect Y is intended for dermatologic and general surgical procedures for the non-invasive treatment of wrinkles and rhytids.

The Acoustic Wave of the TattooStar Effect Y is intended for the activation of connective tissue.

Comparison to: The TattooStar Effect Y is substantially equivalent to the Spectra Laser system and to the TattooStar Y with the same principles of operation, with similar parameters and the with the same indications for use regarding the laser system.
The TattooStar Effect Y is substantially equivalent to the Dermablate Effect with regard to the APL module and the AW module with nearly the same parameters and the same intended use. The APL module of the TattooStar Effect Y is also substancially equivalent to the Ellipse Flex PPT with similar specifications and almost the same intended use.
The TattooStar Effect Y is substancially equivalent to the Aluma system with regard to the RF module with similar

parameters and the same intended use.

Nonclinical Performance Data:	None
Clinical Performance Data:	In vivo study for the removal of wrinkles by means of Radiofrequency.
Conclusion:	The TattooStar Effect Y is another safe and effective device for the incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair and skin resurfacing procedures. When equipped with optional modules, the TattooStar Effect Y is a safe and effective device for permanent hair reduction, treatment of vascular and pigmented lesions and inflammatory acne, for dermatologic and general surgical procedures for the non-invasive treatment of wrinkles and rhytids and for the activation of connective tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ASCLEPION LASER TECHNOLOGIE GmbH
% Ms. Antje Katzer
Product Management and International Regulatory Affairs
Bruesseler Str. 10
07747 Jeana
Germany

MAY 11 2012

Re: K112669
Trade/Device Name: TattooStar Effect Y
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 4, 2012
Received: May 9, 2012

Dear Ms. Katzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K112669

Device Name: TattooStar Effect Y

Indications for Use:

The TattooStar Effect Y laser is indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology and the removal of tattoos, pigmented lesions, vascular lesions and unwanted hair and skin resurfacing procedures.
Depending on the wavelength selected, the indications are as follows:

1064 nm:	Removal of black and blue tattoo color
	Removal of unwanted hair
	Skin resurfacing
532 nm:	Removal of pigmented lesions (including but not limited to lentigo benigna, hyperpigmented burn and boil scar, naevus Ota / Ito, freckles, Becker naevi, Café-au-lait spots)
	Removal of red tattoo color
	Removal of minor vascular lesions
585 nm:	Removal of sky blue tattoo color

The Asclepion Pulsed Light of the TattooStar Effect Y is intended for permanent hair reduction, treatment of vascular lesions, pigmented lesions and inflammatory acne.
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	Vascular lesions, skin type III-IV
	Pigmented lesions, skin type I-IV
650 - 1200 nm:	Hair removal of black hair, skin type IV

The Radiofrequency is intended for dermatologic and general surgical procedures for non-invasive treatment of wrinkles and rhytids.

The Acoustic Wave is intended for the activation of connective tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K112669